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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,583	06/03/1998	KENNETH M. WEISMAN	W1068/20011	2991

7590 04/07/2003

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EXAMINER
OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	31

DATE MAILED: 04/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/089,583	WEISMAN ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE f this c mmunicati n appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,5-13,16,17,19,20,22,23,25,27 and 28* is/are allowed.

6)☒ Claim(s) *1,2,4,14,15,18,21,24,26 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Respons to Arguments

The following is in response to the amendment filed 1/14/03:

An action on the merits of claims 1-29 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting Rejection

The double patenting rejection has been overcome through applicant's submission of a terminal disclaimer over U.S. Patent No. 6,197,337.

Claim Rejections - 35 USC § 112

112(1)

The rejection of claims 1, 2, 4, 14, 15, 18, 29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons of record.

The instant specification invites the skilled artisan to experiment. The factors which must be considered in determining undue experimentation are set forth in In re Wands 8USPQ 2d 1400. The factors include:

1) quantity of experimentation necessary,
2) the amount of guidance presented,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the predictability of the art,
7) breath of the claims and the
8) level of skill in the art.

Quantity of experimentation necessary, Amount of guidance presented, Presence or Absence of working examples

Claims 1, 2, 4, 14, 15, 18, 29 are drawn to a method of decreasing atherosclerosis and its complications comprising administering an amount of a substance which acts to decrease or inhibit the levels of testosterone or non-steroidal antiandrogen. decreasing atherosclerosis and its complications via administration of finasteride, inhibitors of LHRH or GnRH, bicalutamide, flutamide and nilutamide.

Applicant provides guidance via a retrospective questionnaire wherein patients administered with agents such as finasteride, inhibitors of LHRH or GnRH, bicalutamide, flutamide and nilutamide reported fewer heart attacks; however, applicant has not provided support commensurate to a claim of "any substance" which inhibits levels of testosterone or non-steroidal antiandrogen being correlative to a reduction in atherosclerosis or myocardial infarction. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved. There is no data wherein radiologic or diagnostic tools were employed to show, with regards to blood flow rates or angiograms, that either atherosclerotic conditions were present prior to the study or that there was a clear correlation between the administration of a broad class of inhibitors of testosterone/an androgen and a reduction in atherosclerosis.

Predictability of the art/State of the art

The state of the art of cardiology is such that there are many factors leading to atherosclerosis or myocardial infarction, for instance diet has a significant role in atherosclerosis. In the data presented to the patent office on 11/12/1999, applicant provides data on the incidence of certain accepted risk factors between the control group and those administered with an inhibitor of testosterone or an androgen; however, one accepted risk factor that was not reported nor considered was that of diet. According to Goodman and Gilman's The Pharmaceutical Basis of Therapeutics, interpatient and intrapatient variation in disposition of a drug must be taken into account in choosing a drug regimen.

Different individuals vary in the magnitude of their response to the same concentration of a single drug or to similar drugs when the appropriate correction has been made for differences in potency, maximal efficacy and slope (pp 65-68).

The prior art indicates that climacteric disorders during aging in males such as increased incidence of cardiovascular diseases may be associated with the reduction in testosterone or steroid precursor levels (U.S. Patent No. 5872114, col.3-col.4; U.S. Patent no. 5,906,987, col. 1-col.2). Thus the state of the art requires a well designed and well executed clinical trial wherein homogenous populations of patients must be selected and appropriate control groups found are utilized in order to show data which teaches away from that which has been established in the prior art. The instant specification does not take into consideration that the difference in heart attack rates by the patients may be attributed to diet especially since the patients weren't monitored or controlled for their dietary intake prior to the administration of the questionnaire.

Applicant does not provide commensurate data on a broad range of compounds that inhibit testosterone and show a decrease in an existing condition of atherosclerosis or the prevention of the onset of atherosclerosis. Since applicant has not clearly established that the reduction in atherosclerosis may be accomplished by a broad number of testosterone inhibitors, it is not evident that one of skill in the art may rely upon the administration of any testosterone inhibitor to reduce the incidence of atherosclerosis.

Applicant's arguments based on any references not of record or provided to the examiner of record on a PTO 1449 have not been considered. Applicant should note that the rejection is a scope of enablement rejection. Therefore, the examiner has recognized that there may be enablement for the compounds of finasteride, goserelin and leuprolide, however, the claim language is drawn broadly to any inhibitor of testosterone being capable of treating atherosclerosis for which applicant has not provided guidance commensurate to the scope of the claim. Applicant's arguments do not address the scope of enablement rejection

with regards to the breadth of the scope of the claims and the support provided therefore, as such the rejection cited supra is maintained.

112(2)

The rejection of claims 21, 24 and 26 under 35 U.S.C. 112(2) is maintained for the reasons of record. Applicant has not provided a response to this rejection in the form of argument nor amendment.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.